

Recommendations for the Identification of Chronic Hepatitis C virus infection Among Persons Born During 1945-1965



MMWR August 17, 2012

Prepared by :

**The National Viral Hepatitis Technical Assistance Center at
the NYS Department of Health – AIDS Institute**

Trends in Hepatitis C in the US

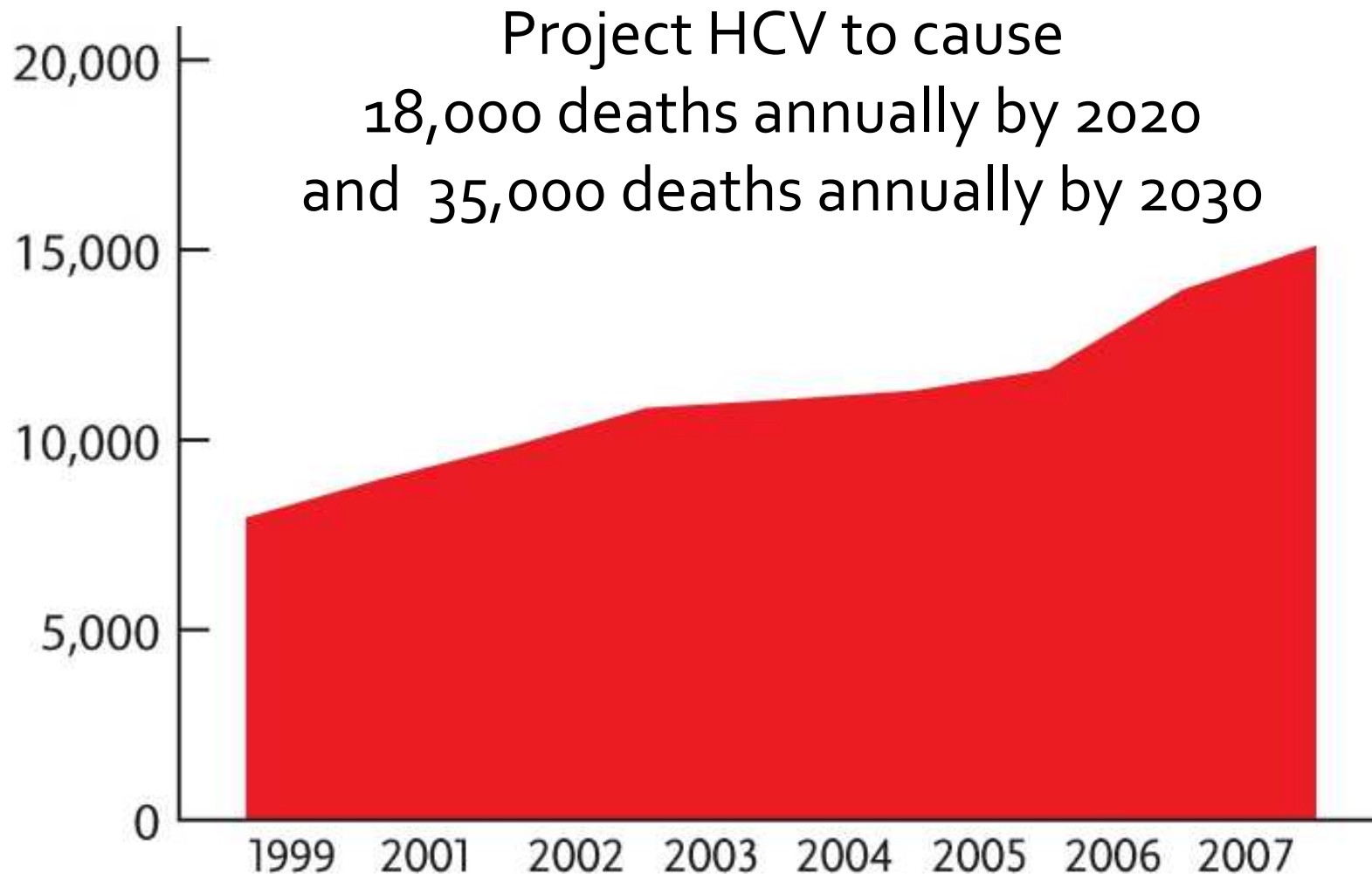
- 2.7 – 3.9 million (1.0-1.5%) persons living with Hepatitis C virus (HCV) infection in the US
- 17,000 new infections in 2010
- Acute HCV infection is usually asymptomatic
- 75-85% of HCV infections persist as chronic infections placing at risk for:
 - Liver cirrhosis
 - Hepatocellular carcinoma (HCC)
 - Extrahepatic complications
- 15,106 deaths were attributable to HCV, in 2007

Increasing Morbidity and Mortality Related to Hepatitis C

- HCV is a major cause of liver disease
 - Leading indication for liver transplantation
 - Leading cause of HCC (approx.50% of HCC incident)
- Over the next 40-50 years, a projected:
 - 1.76 million with untreated HCV infection will develop cirrhosis
 - 400,000 will develop HCC
 - 1 million will die from HCV-related complications
- Substantial HCV-related costs¹
 - Exceeds \$5 billion annually
 - 2010-2019 estimated costs total \$54.2 billion

¹ McGarry et al. "Economic Model of a Birth Cohort Screening program for Hepatitis C" Hepatology 2012; 55:1344-1355

Hepatitis C – Related deaths



Benefit of HCV Diagnosis and Care

- Early clinical evaluation and ongoing monitoring
 - Treatment response decreases as liver disease progresses
- Take measures to protect their liver from further harm
 - Vaccination against Hepatitis A and B
 - Decrease or eliminate alcohol consumption
 - Counseling on interactions between herbal supplements, over the counter, and prescription medications
 - Counseling to encourage weight loss for persons who have a BMI ≥ 25
- Reduce the risk of transmission to others

Benefits of HCV treatment

- Treatment recommended for HCV-infected persons w/signs of bridging fibrosis, septal fibrosis or cirrhosis
- Elimination of HCV infection is possible – known as Sustained Virologic Response (SVR)
- HCV therapy shown to be effective
 - Approx. 40% SVR within 48 weeks w/PEG/RIBA
 - Approx. 70% within 24 weeks w/ PEG/RIBA and direct acting agents
 - At least 22 new therapies in phase I/II trials
- SVR associated with :
 - 54% reduction in all-cause mortality
 - Lower rates of liver related death and decompensated cirrhosis

New Recommendations Augment Existing CDC Testing Guidelines

National Hepatitis C Prevention Strategy

2001



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MMWR™

Morbidity and Mortality Weekly Report

www.cdc.gov/mmwr

Recommendations and Reports

April 10, 2009 / Vol. 58 / No. RR-4

Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents

Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America

INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Current CDC Risk and Medical Indication-Based Guidelines

- **Had ever injected illegal drugs**
- **Were ever on chronic hemodialysis**
- **Received blood transfusions or solid organ transplants before July 1992**
- **Received clotting factor concentrates made before 1987**
- **Known exposure to Hepatitis C**
- **Living with HIV**
- **Has signs or symptoms of liver disease (persistent abnormal ALT)**
- **Children born to mothers who have Hepatitis C**

New CDC Recommendations for HCV testing

- Adults born from 1945 through 1965 should receive **one-time** testing for HCV without prior ascertainment of HCV risk factor status
- All persons with identified HCV infection should receive a brief alcohol screening and intervention as appropriate, followed by referral to appropriate care and treatment service for HCV infection and related conditions.

Rationale for Augmenting HCV Testing Recommendations

- Limited effectiveness of current testing strategies
- Increasing morbidity and mortality of chronic HCV infection
- Benefits of diagnosis and care
- Benefits of HCV treatment

Limited Effectiveness of Current Testing Strategy

- 45-85% of adults with chronic hepatitis C are unaware of their infection
 - Among high risk populations 17-87% are unaware of their infection status
- 45% of persons ever infected with HCV report no known risk
- ALT screening misses > 50% of chronic cases

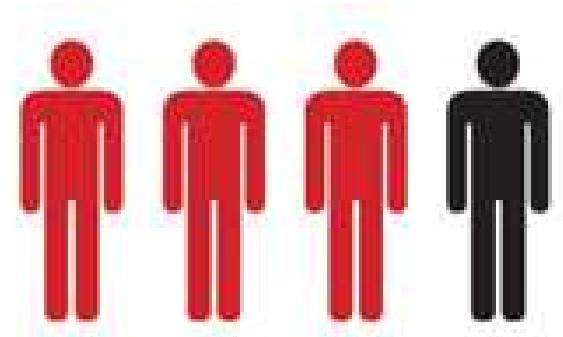
Limitations of Risk and Medical Indication-Based Screening

- General Barriers to HCV screening
 - Inadequate health insurance coverage
 - Limited access to regular healthcare
 - Limited physician knowledge and experience of hepatitis serology and treatment
- Barriers to Risk Based Screening
 - Physician reluctance to ask sensitive questions about high-risk behaviors
 - Reliability of patient recall and reporting of risk behaviors

Why 'Baby Boomers'?

- Selection of 1945-1965 birth cohort based on:
 - High prevalence of chronic infection
 - High incidence of HCV infection in the remote past
 - Long period of subclinical infection
 - Proportion of burden
 - Race/ethnicity and sex stratifications
 - Cost per chronic case identified
 - Familiarity of the 'baby boomer' sub-population

**More than 75 percent of
American adults with hepatitis
C are baby boomers**



HCV Prevalence and Demographics in Persons Born 1945-1965

- Persons born between 1945-1965 are five times more likely to be infected with HCV
 - HCV Prevalence 3.25% among 1945-1965 birth cohort vs. 0.88% among individuals outside the birth cohort.
- 1.94 million chronically infected
- Represent 73% of all HCV-associated mortality
- 31.5% lack health insurance
- 57.8% reported drinking an average of two or more alcoholic drinks per day.
- 80% lack Hepatitis A/B vaccination

Method for Developing Expanded HCV Screening Recommendations

- HCV Birth Cohort Testing Work Group
 - DVH Steering Committee
 - Internal DVH workgroup
 - External consultant participation, including representatives of federal agencies, state and local health departments, professional and medical specialty associations, community and advocacy groups.
 - Teleconference
 - GRADE workshop
 - Two-Day Consultation Aug. 2011
 - Resource implications
- Peer review by three independent reviewers, Oct.-Nov 2011
- Public comment Apr.-Jun. 2012

Factors Considered When Determining the Recommendations

- Two-staged comprehensive literature review
 - Stage 1: Selection of the birth cohort based on HCV infection prevalence
 - Stage 2: Evaluate the benefit and harm of testing of persons born 1945-1965 on patient important outcomes
- Used Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework
 - Quality of evidence
 - Balance between benefits and harms
 - Values and preferences
 - Resource implications

Patient-Important Outcomes Considered

- All-cause Mortality
- Hepatocellular Carcinoma (HCC)
- Sustained Viral Response (SVR)
- Serious adverse events (i.e. treatment related side-effects)
- Quality of life
- Alcohol use
- Other outcomes, but no relevant studies identified
 - HCV transmission
 - Insurability
 - Reassurance and false reassurance of testing negative
 - Anxiety caused by testing

Key Results

- Benefits outweigh the potential harms
 - Key benefits: SVR, reduced liver related morbidity and all cause mortality, clinician directed intervention on alcohol use.
 - Potential harms: anxiety, insurability, treatment related adverse events.
- HCV testing is widely accepted

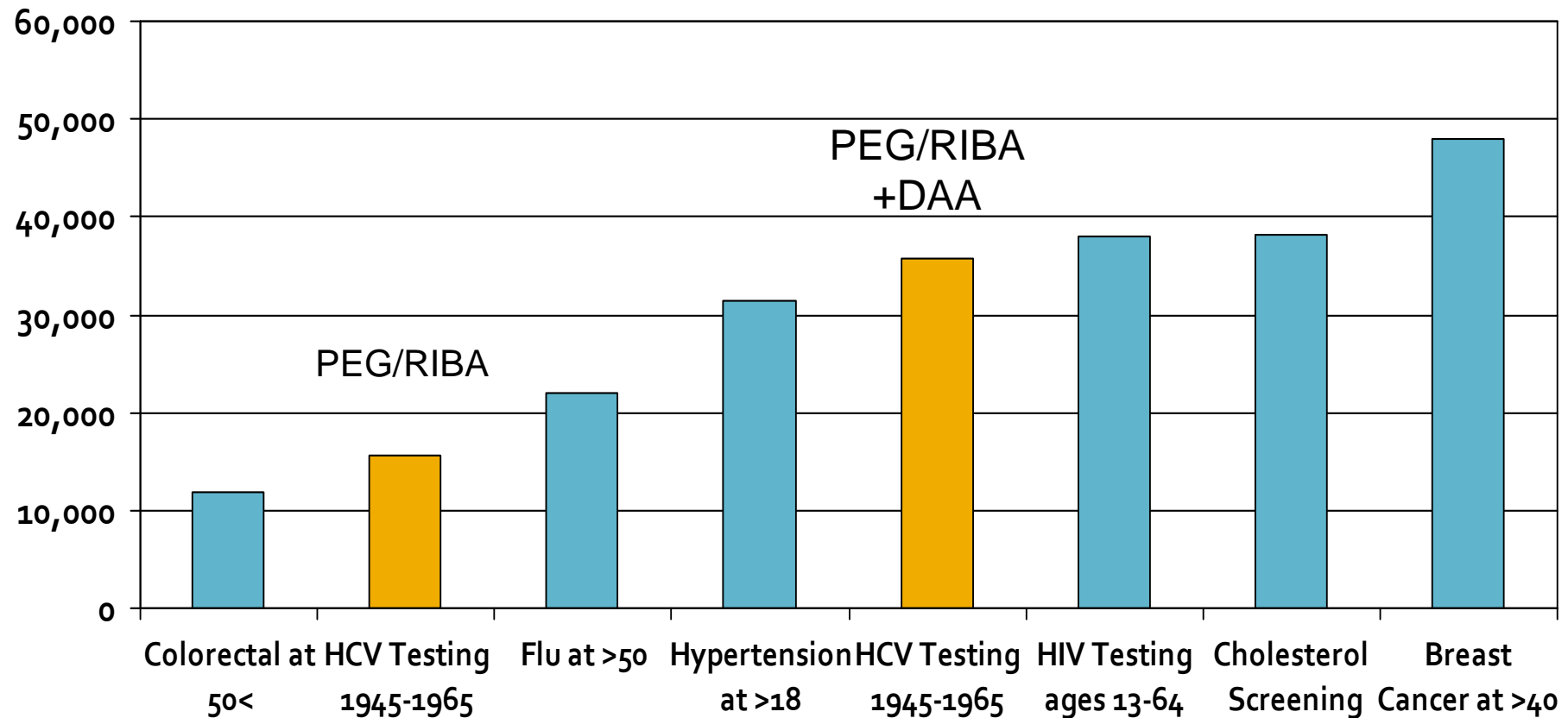
Health and Cost Impact of HCV Testing of Persons Born 1945-1965

Outcome	Birth Cohort Testing with Therapy	
	PegIFN-Riba (PR)	PegIFN-Riba + TVR
Additional Identified Cases	809,000	809,000
Cirrhosis cases averted	138,000	203,000
Decompensated cirrhosis cases averted	50,000	74,000
Hepatocellular carcinoma cases averted	32,000	47,000
Transplants averted	11,000	15,000
Deaths from hepatitis C virus averted	82,000	121,000
Medical costs averted	\$1.5b	\$2.5b
Cost/QALY gained (Societal)	\$15,700	\$35,700

Rein DB, Smith BD, et al.. *Ann Intern Med.* 2012;156:263-270, 2011.

Comparison of HCV Cost Effectiveness with other Routine Preventive Services

Cost in \$ /Quality Adjusted Life-Years



Conclusion

- Expansion of HCV testing recommendations to include a one-time screening of all individuals born between 1945 and 1965 will :
 - Help to identify unrecognized infections
 - Limit transmission
 - Facilitate HCV-infected persons receiving beneficial care and treatment before the onset of severe HCV-related disease

Understanding how CDC recommendations relate to USPTF

USPTF

- Independent panel of clinical experts; established by Congress
- Evaluate and make recommendations for preventive services

Focus:

- Context of primary care settings
- Patient – provider interaction
- Consider direct harm & benefits for the patient


CDC

- Operating division of the Department of Health and Human Services (DHHS)
- Evaluate and make recommendations for preventive services

Focus:

- Broader PH focus, including setting outside of primary care
- Consider broader benefits & harms, ex. absence of action and future disease transmission

Tools Available to Promote Expanded Recommendations



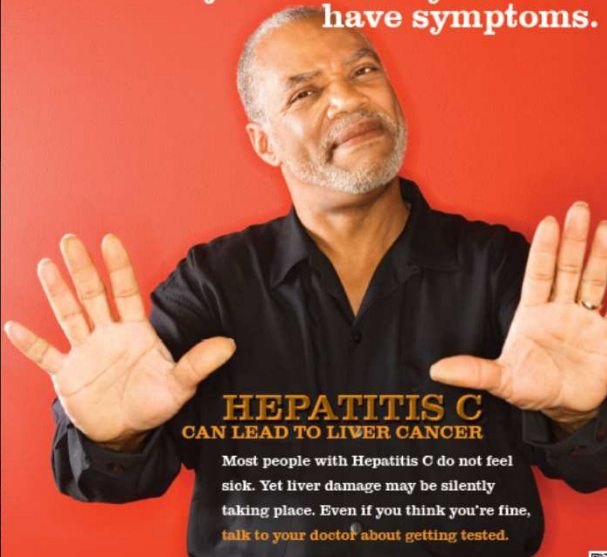
BORN FROM 1945 to 1965?

BABY BOOMERS HAVE THE HIGHEST RATES OF HEPATITIS C.

Talk to your doctor about getting tested.
Early detection can save lives.


www.cdc.gov/knowmorehepatitis

Don't say
“I'm all good”
just because you don't
have symptoms.



**HEPATITIS C
CAN LEAD TO LIVER CANCER**

Most people with Hepatitis C do not feel sick. Yet liver damage may be silently taking place. Even if you think you're fine, **talk to your doctor about getting tested.**

 U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

www.cdc.gov/knowmorehepatitis

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Management of Persons tested for HCV infection

- Negative anti-HCV test results
 - Inform no HCV infection, unless recent risk
- Positive anti-HCV
 - Follow-up HCV nucleic acid testing (NAT) is needed to determine if current or past resolved HCV infection
 - If **negative** NAT test, no HCV infection and no follow-up needed
 - If **positive** NAT result:
 - Inform of HCV infection and need for further medical evaluation and ongoing monitoring.
 - Evaluate alcohol use and provide brief alcohol intervention if indicated.

Alcohol-Use Reduction

- Alcohol screening and brief interventions (SBI)
 - Screening for excessive alcohol consumption
 - Brief counseling
 - Referral to specialized alcohol treatment
 - Ex. AUDIT
- Reduce number of drinks consumed/week
- Reduce episode of binge drinking

Linkage to Care and Treatment

- To improve health outcomes, individuals testing positive for HCV must be provided with appropriate care and treatment.
- Barriers to linkage to care
 - Uninsured or underinsured
 - Failure of provider to provide referrals
 - Failure of patients to follow-up on referrals
 - Drug or alcohol use
- Strategies to link to care
 - Active linkage to care
 - Coordination between primary care and specialist